DAC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Shai N. Gozani et al.
Serial No.:	10/075,217
Filing Date:	02/14/2002
Title:	APPARATUS AND METHOD FOR PERFORMING NERVE CONDUCTION STUDIES WITH LOCALIZATION OF EVOKED RESPONSES
Group Art Unit:	3736
Examiner:	Michael Apanius
Attorney's Docket No.:	NEURO-NRO-008

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, PO BOX 1450, ALEXANDRIA, VA 22313-1450, ON:

January 8, 2008
(DATE OF DEPOSIT)

Margaret M. Slezak
(NAME OF ATTORNEY)

(SIGNATURE)

January 8, 2008
(DATE OF SIGNATURE)

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PETITION TO WITHDRAW HOLDING OF ABANDONMENT UNDER 37 CFR 1.181

Applicants respectfully petition the Director to withdraw the Notice of Abandonment issued in connection with the above-identified patent application, inasmuch as a response to the outstanding Official Action issued on February 23, 2007 was filed with the U.S. Patent and Trademark Office on August 23, 2007.

A statement of the facts involved is provided hereinbelow.

An Official Action was mailed by Examiner Michael Apanius on February 23, 2007.

On August 23, 2007, Applicants submitted a Time Extension Petition, an Amendment, a Certificate of Mailing, a check for

$510.00 and a return receipt postcard to the U.S. Patent and Trademark Office. A copy of the Time Extension Petition and a copy of the Amendment are enclosed for the convenience of the U.S. Patent and Trademark Office.

On August 29, 2007, Applicants received the return receipt postcard indicating that the Time Extension Petition, Amendment, Certificate of Mailing, check for $510.00 and return receipt postcard were received at the U.S. Patent and Trademark on August 27, 2007 (copy enclosed).

A Notice Of Abandonment was mailed on December 11, 2007 which indicated that the above-identified patent application was abandoned for "failure to timely file a proper reply to the Office letter mailed on 23 February 2007".

In view of the fact that a timely response was filed, Applicants respectfully request that the Director withdraw the Notice of Abandonment and enter the amendment filed on August 23, 2007 in the above-identified patent application.

In the event that any fees may be required in this matter, please charge the same to Deposit Account No. 16-0221.

Thank you.

Respectfully submitted,

Margaret M. Slezak
Registration No. 55,625
Pandiscio & Pandiscio, P.C.
470 Totten Pond Road
Waltham, MA 02451-1914
Tel. No. (781) 290-0060

MMS/NEURONRO008.PET

PATENT

Due Date: 08/23/2007
Mailing Date: 08/23/2007
Mailing: MMS/jc

Application No.
Applicants: Shai N. Gozani et al.

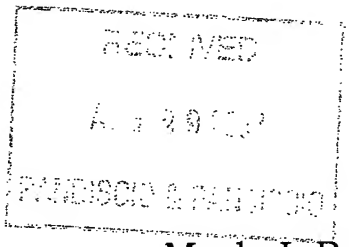
Serial No. 10/075,217 Patent No. Docket No. NEURO-NRO-008

Title: **APPARATUS AND METHOD FOR PERFORMING NERVE CONDUCTION STUDIES WITH LOCALIZATION OF EVOKED RESPONSES**

- ☐ Specification and Claims
- ☐ Abstract
- ☐ Declaration and Power of Attorney
- ☐ Drawings (sheets)
- ☐ Information Disclosure ~~Statement~~
- ☐ Assignment
- ☒ Time Extension Petition (3 months)
- ☐ Small Entity Verification

- ☐ PCT REQUEST
- ☐ PCT Application
- ☐ Status Inquiry
- ☐ Other _____

- ☒ Check $510.00
- ☒ Amendment (21 sheets)
- ☐ Transmittal Letter
- ☒ Certificate of Mailing
- ☐ Express Mail Certificate
- ☐ Maintenance Fee Transmittal
- ☐ Notice of Appeal
- ☐ Issue Fee Transmittal
- ☐ Brief (3 copies)
- ☐ PCT Fee Calculation Sheet
- ☐ Request for Foreign License
- ☐ Power of Attorney



Mark J. Pandiscio
Pandiscio & Pandiscio, P.C.
470 Totten Pond Road
Waltham, MA 02451

COPY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Shai N. Gozani et al.
Serial No.:	10/075,217
Filing Date:	02/14/2002
Title:	APPARATUS AND METHOD FOR PERFORMING NERVE CONDUCTION STUDIES WITH LOCALIZATION OF EVOKED RESPONSES
Group Art Unit:	3736
Examiner:	Michael Apanius
Attorney's Docket No.:	NEURO-NRO-008

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PETITION FOR AUTOMATIC EXTENSION OF TIME TO RESPOND

Applicants hereby petition for a three (3) month extension of time to respond to the outstanding OFFICIAL ACTION mailed February 23, 2007 with respect to the above-identified patent application, thereby extending the time for response from May 23, 2007 to August 23, 2007.

A check in the amount of $ 510.00 is enclosed to cover the cost of the petition fee. This petition fee has been calculated on the basis of a Small Entity status.

In the event that any additional fees may be required to be paid in connection with this matter, please charge the same, or credit any overpayment, to Deposit Account No. 16-0221. A duplicate copy of this Petition is enclosed for the convenience of the Office.

Thank you.

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, PO BOX 1450, ALEXANDRIA, VA 22313-1450, ON:

August 23, 2007
(DATE OF DEPOSIT)

Margaret M. Slezak
(NAME OF ATTORNEY)

(SIGNATURE)

August 23, 2007
(DATE OF SIGNATURE)

Respectfully submitted,

Margaret M. Slezak, Esq.
Registration No. 55,625
Pandiscio & Pandiscio, P.C.
470 Totten Pond Road
Waltham, MA 02451-1914
Tel. No. (781) 290-0060

JC2/NEURONRO008.EXT2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

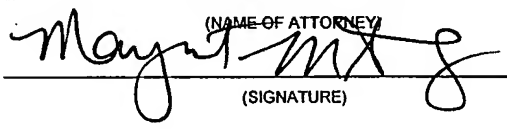
In re Application of:	Shai N. Gozani et al.
Serial No.:	10/075,217
Filing Date:	02/14/2002
Title:	APPARATUS AND METHOD FOR PERFORMING NERVE CONDUCTION STUDIES WITH LOCALIZATION OF EVOKED RESPONSES
Group Art Unit:	3736
Examiner:	Michael Apanius
Attorney's Docket No.:	NEURO-NRO-008

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, PO BOX 1450, ALEXANDRIA, VA 22313-1450, ON:

August 23, 2007
(DATE OF DEPOSIT)

Margaret M. Slezak
(NAME OF ATTORNEY)


(SIGNATURE)

August 23, 2007
(DATE OF SIGNATURE)

Sir:

AMENDMENT

Responsive to the Official Action issued February 23, 2007 in the above-identified patent application, please:

cancel claim 75;

amend claims 24-30, 32, 34-36, 48-49, 51, 53, 63-65, 68-70 and 74; and

add new claims 76-90;

all as set forth in the following section entitled "Amended Claims".

AMENDED CLAIMS

1 - 23. (Canceled)

24. (Currently Amended) A method for assessing physiological function in an individual, comprising:

(a) placing a sensor superficially on an individual, said sensor comprising a stimulator, a detector, and a flexible connector formed integral with and serving as a mechanical and electrical connection between said stimulator and said detector:

said stimulator being shaped to fit a first anatomical site and configured to generate a stimulus and apply said stimulus to stimulate a nerve at said first anatomical site;

said detector being shaped to fit a second anatomical site, said detector comprising a plurality of electrodes each configured to detect a response signal generated at said second anatomical site in response to said stimulus, said detector being made so that said electrodes have fixed positions proximate one another; and

said connector being configured to mechanically orient said stimulator and said detector relative to one another and automatically position said detector substantially adjacent to said second anatomical site when said stimulator is placed substantially adjacent to said first anatomical site on the surface of an individual, whereby said electrodes are located at proximate points along said surface; and

(b) performing nerve conduction studies with at least one of said electrodes to assess physiological function in an individual;

wherein said nerve conduction studies comprises:

(c) operating said stimulator to stimulate said first anatomical site and monitoring said plurality of electrodes to detect response signals produced at said second anatomical site in response to the stimulation at said first anatomical site;

(~~c~~d) processing the response signals detected by said electrodes, said processing involving an evaluation of selected parameters of each of said response signals and a comparison of said response signals according to the evaluated selected parameters;

(~~d~~e) ~~determining from~~ selecting on the basis of said comparison of said response signals processed in step (~~c~~d)at least one electrode detecting a response signal characteristic of said second anatomical site; and

(~~e~~f) performing said nerve conduction studies according to step (c) ~~of step (b)~~ with said at least one electrode selected in step (~~d~~e).

25. (Currently Amended) The method of claim 24 wherein in step (f) said nerve conduction studies comprise measurement of an F-wave latency.

26. (Currently Amended) The method of claim 24 wherein in step (f) said nerve conduction studies comprise measurement of a motor latency.

27. (Currently Amended) The method of claim 24 wherein in step (f) said nerve conduction studies comprise measurement of a sensory latency.

28.(Currently Amended) The method of claim 24 wherein in step (f) said nerve conduction studies comprise measurement of a sensory amplitude.

29. (Currently Amended) The method of claim 24 wherein in step (d) said processing comprises amplitude comparison between a plurality of response signals generated at said second anatomical site.

30. (Currently Amended) The method of claim 24 wherein in step (d) said processing comprises frequency spectrum comparison between a plurality of response signals generated at said second anatomical site.

31. (Previously Presented) The method of claim 24 wherein at least one response signal generated at said second anatomical site comprises peripheral evoked potentials.

32.(Currently Amended) The method of claim 29 wherein in step (d) said amplitude comparison comprises maximal peak to peak amplitude.

33. (Previously Presented) The method of claim 30 wherein said frequency spectrum comparison comprises discrete Fourier transform analysis of said plurality of response signals generated at said second anatomical site and comparison of the spectral components of said plurality of response signals.

34. (Currently Amended) The method of claim 33 wherein ~~selected electrodes comprise electrodes with~~ in step (d) said at least one electrode detects response signals that have more energy at low frequencies.

35. (Currently Amended) The method of claim 24 wherein the nerve conduction studies of step (f) involve detecting at least one signal generated at said second anatomical site ~~comprises~~ comprising compound muscle action potential.

36. (Currently Amended) The method of claim 24 wherein said at least one electrode selected in step (d) is located over a muscle motor point at ~~one signal generated at~~ said second anatomical site ~~is recorded over a motor point~~.

37-47. (Canceled)

48. (Currently Amended) A method for assessing physiological function in an individual, comprising:

(a) providing a sensor for superficial application to an individual, said sensor comprising:

a stimulator for generating a nerve stimulus, said stimulator being shaped to fit a first anatomical site whereby application of said stimulus stimulates a nerve at said first anatomical site; and

a detector shaped to fit a second anatomical site, said detector comprising a plurality of electrodes each capable of detecting a signal generated at said second anatomical site in response to said stimulus applied at said first anatomical site, with said electrodes being fixed in spaced relation with one another, and

a flexible connector connecting said stimulator to said detector to form an integral unitary structure;

said flexible connector being constructed and shaped to effect mechanical localization of said detector relative to said stimulator whereby said detector will be automatically ~~position~~ positioned ~~said detector~~ substantially adjacent to said second anatomical site when said stimulator is placed substantially adjacent said first anatomical site on the surface of an individual;

(b) placing said sensor superficially on an individual so that said stimulator is located at and fits said first anatomical site and said detector is located at and fits said second anatomical site; and

(c) performing nerve conduction studies with said sensor to assess physiological function in an individual, said studies comprising (1) causing said stimulator to generate a stimulus on said individual at said first anatomical site, (2) causing said electrodes of said detector to detect response signals generated at said second anatomical site in response to said stimulus applied at said first anatomical site, and (3) ~~evaluating~~ recovering said response signals;

(d) processing the recovered response signals generated at said second anatomical site and detected by said electrodes to effect selection of ~~select~~ at least one electrode detecting a response signal characteristic of said second anatomical site, said selection involving evaluating two or more selected parameters of said response signals and comparing said response signals according to said evaluated selected parameters; and

(e) performing ~~the~~ additional nerve conduction studies as specified in step (c) with the at least one electrode selected in step (d).

49. (Currently Amended) The method of claim 48 wherein in step (d) said processing ~~further~~ comprises amplitude comparison between a plurality of response signals generated at said second anatomical site.

50. (Previously Presented) The method of claim 49 wherein said amplitude comparison comprises maximal peak to peak amplitude.

51. (Currently Amended) The method of claim 48 wherein in step (d) said processing comprises frequency spectrum comparison between a plurality of response signals generated at said second anatomical site.

52. (Previously Presented) The method of claim 51 wherein said frequency spectrum comparison comprises discrete Fourier transform analysis of said plurality of response signals generated at said second anatomical site and comparison of the spectral components of said response signals.

53. (Currently Amended) The method of claim 52 wherein ~~said at least one selected electrode comprises electrodes with more energy at low frequencies~~ the at least one

electrode selected in step (d) is selected because the response signals detected by said at least one electrode has more energy at low frequencies.

54. (Previously Presented) The method of claim 48 wherein each of said response signals generated at said second anatomical site comprises peripheral evoked potentials.

55. – 62. (Canceled)

63. (Currently Amended) Apparatus for assessing physiological function in an individual, the apparatus comprising:

a sensor comprising: a stimulator, a detector, and a flexible connector formed integral with and serving as a mechanical and electrical connection between said stimulator and said detector;

said stimulator being shaped to fit a first anatomical site and configured to generate a stimulus and apply said stimulus to stimulate a nerve at said first anatomical site;

said detector being shaped to fit a second anatomical site, said detector comprising a plurality of electrodes each configured to detect a response signal generated at said second anatomical site in response to said stimulus with the positions of said electrodes being fixed in relation to one another; and

said connector being configured to mechanically orient said detector relative to said stimulator and to automatically position said detector substantially adjacent to said second anatomical site when said stimulator is placed substantially adjacent to said first anatomical site on the surface of an individual, whereby said electrodes are positioned at different points along said second anatomical site;

wherein the apparatus is configured to select, from the plurality of response signals detected ~~at~~ by the plurality of detector electrodes, at least one electrode

detecting a response signal characteristic of said second anatomical site, with the selection of said at least one electrode being determined by an algorithm involving evaluation of several parameters of signals detected by said electrodes.

64. (Currently Amended) Apparatus of claim 63 wherein said ~~selecting~~ selection of said at least one electrode comprises amplitude comparison between a plurality of response signals generated at said second anatomical site.

65. (Currently Amended) Apparatus of claim 63 wherein said ~~selecting~~ selection of said at least one electrode comprises frequency spectrum comparison between a plurality of response signals generated at said second anatomical site.

66. (Previously Presented) Apparatus of claim 64 wherein said amplitude comparison comprises maximal peak to peak amplitude.

67. (Previously Presented) Apparatus of claim 65 wherein said frequency spectrum comparison comprises discrete Fourier transform analysis of said plurality of response signals generated at said second anatomical site and comparison of the spectral components of said plurality of response signals.

68. (Currently Amended) Apparatus of claim ~~67~~ 63 wherein ~~selected electrodes comprise electrodes with more energy at low frequencies~~ the selection of said at least one electrode involves a comparison of the power spectrum densities of detected response signals.

69. (Currently Amended) Apparatus for assessing physiological function in an individual, comprising:

a sensor comprising:

a stimulator for generating a nerve stimulus, said stimulator being shaped to fit a first anatomical site whereby application of said stimulus stimulates a nerve at said first anatomical site; and

a detector shaped to fit a second anatomical site, said detector comprising a plurality of electrodes each capable of detecting a signal generated at said second anatomical site in response to said stimulus applied at said first anatomical site, said electrodes being in fixed spatial relation to one another; and

a flexible connector connecting said stimulator to said detector to form an integral structure;

said flexible connector being constructed to mechanically orient said stimulator and detector relative to one another and being shaped to automatically position said detector so that said electrodes are substantially adjacent to said second anatomical site when said stimulator is placed substantially adjacent said first anatomical site on the surface of an individual;

wherein the apparatus is configured to determine, from a comparison of selected parameters of the response signals generated at said second anatomical site and detected by said electrodes, at least one electrode detecting ~~a~~an optimum response signal characteristic of said second anatomical site.

70. Currently Amended) Apparatus of claim 69 wherein said determining ~~further~~ comprises amplitude comparison between a plurality of response signals generated at said second anatomical site.

71. (Previously Presented) Apparatus of claim 70 wherein said amplitude comparison comprises maximal peak to peak amplitude.

72. (Previously Presented) Apparatus of claim 69 wherein said determining comprises frequency spectrum comparison between a plurality of response signals generated at said second anatomical site.

73. (Previously Presented) Apparatus of claim 72 wherein said frequency spectrum comparison comprises discrete Fourier transform analysis of said plurality of response signals generated at said second anatomical site and comparison of the spectral components of said response signals.

74. (Currently Amended) Apparatus of claim 73 wherein said at least one ~~selected~~ electrode comprises electrodes that detect signals with more energy at low frequencies.

75. (Canceled)

76. (New) The method of claim 24 wherein said first site is a location over a nerve and said second site is a location over a muscle innervated by said nerve or a location over different portion of said nerve.

77. (New) Apparatus according to claim 63 wherein said sensor comprises a continuous base layer that forms part of said stimulator, said detector and said connector.

78. (New) Apparatus according to claim 69 configured so that the selection of said at least one electrode is accomplished by comparing two or more parameters of each response signal detected by one of said electrodes with like parameters of the response signals detected by others of said electrodes.

79. (New) A method for assessing physiological function in an individual, comprising:

(a) providing a sensor comprising a stimulator, a detector, and a flexible connector formed integral with and serving as a mechanical and electrical connection between said stimulator and said detector:

said stimulator being shaped to fit a first anatomical site and configured to generate an electrical stimulus to stimulate a nerve at said first anatomical site;

said detector being shaped to fit a second anatomical site, said detector comprising a plurality of electrodes each configured to detect response signals evoked by a muscle at said second anatomical site in response to said stimulus, said electrodes being in fixed spatial relation to one another; and

said connector being constructed so as to determine the spatial position of said detector relative to said stimulator and being configured to automatically position said detector substantially adjacent to said second anatomical site when said stimulator is placed substantially adjacent to said first anatomical site on the surface of an individual; and

(b) placing said sensor on an individual so that said stimulator is positioned substantially adjacent to a first anatomical site characterized by a nerve to be studied and said detector is positioned adjacent to a second anatomical site characterized by a muscle associated with said nerve,

(c) operating said stimulator to stimulate said nerve at said first anatomical site;

(d) operating said detector so as to cause said electrodes to detect response signals evoked by said muscle at said second anatomical site in response to the stimulation of said nerve at said first anatomical site;

(e) processing the response signals detected by said electrodes to determine from parameters of said response signals the electrode or electrodes located closest to the motor point of said muscle; and

(f) with said sensor still in place on said individual, performing nerve conduction studies using the detector electrode(s) located closest to the motor point of said muscle.

80. (New) The method of claim 79 wherein said response signals are in the form of biopotentials detected on the skin of said individual overlying said second anatomical site.

81. (New) The method of claim 79 wherein step (e) involves determining the latency, peak-to-peak amplitude and slope of said response signals and determining therefrom the detector electrode(s) located closest to the muscle point of said muscle.

82. (New) The method of claim 79 wherein the nerve conduction studies performed according to step (f) comprise measurement of an F-wave latency.

83. (New) The method of claim 79 wherein the nerve conduction studies performed according to step (f) comprise measurement of a motor latency.

84. (New) The method of claim 79 wherein the nerve conduction studies performed according to step (f) comprise measurement of compound muscle action potential.

85. (New) The method of claim 79 wherein the processing of step (e) comprises amplitude comparison between a plurality of response signals generated at said second anatomical site.

86. (New) The method of claim 79 wherein said processing of step (e) comprises frequency spectrum comparison between a plurality of response signals generated at said second anatomical site.

87. (New) The method of claim 79 wherein the nerve conduction studies performed according to step (f) are conducted by (1) causing said stimulator to generate a stimulus on said individual at said first anatomical site, (2) causing said selected electrodes of said detector to detect response signals generated at said second anatomical site in response to said stimulus applied at said first anatomical site, and (3) evaluating said response signals detected by said selected electrodes by measuring one or more of the following parameters: F-wave latency, F-wave amplitude, distal motor latency (DML), compound action potential (CMAP) amplitude, refractory period, activity dependence, and stimulation threshold.

88. (New) The method of claim 79 wherein the determination of the electrode or electrodes located closest to the muscle point of said muscle according to step (e) is accomplished by means of an algorithm that involves evaluation of several selected parameters of the response signals detected by said plurality of electrodes.

89. (New) A method for conducting nerve conduction studies of a nerve segment or muscle in an individual, said method comprising:

(a) providing a sensor adapted for application superficially on an individual, said sensor comprising a stimulator, a detector, and a flexible connector formed integral with and serving as a mechanical and electrical connection between said stimulator and said detector, with said stimulator, detector and connector having a common substrate whereby they form an integral unit:

said stimulator being shaped to fit a first anatomical site constituting a first superficial location over a nerve of an individual and configured to generate a stimulus and apply said stimulus to stimulate said nerve;

said detector being shaped to fit a second anatomical site constituting a second superficial location over a muscle innervated by said nerve or a segment of that nerve,

said detector comprising a plurality of electrodes each configured to detect a response signal generated at said second anatomical site in response to said stimulus, said detector being made so that said electrodes have fixed positions proximate one another; and

said connector being configured to mechanically orient said stimulator and said detector relative to one another whereby to automatically position said detector substantially adjacent to said second anatomical site when said stimulator is placed substantially adjacent to said first anatomical site, whereby said electrodes are located at proximate points along said second anatomical site;

(b) placing said sensor on an individual so that said stimulator is located superficially at said first anatomical site and said detector is located superficially at said second anatomical site;

(c) operating said stimulator to stimulate said first anatomical site and monitoring said plurality of electrodes to detect response signals produced at said second anatomical site in response to the stimulation at said first anatomical site;

(d) processing the response signals detected by said electrodes, said processing involving an evaluation of two or more selected nerve conduction parameters of each of said response signals and a comparison of said response signals according to the evaluated selected parameters;

(e) selecting on the basis of said comparison of said selected nerve conduction parameters of said response signals processed in step (d) at least one electrode detecting an optimal response signal characteristic of said second anatomical site; and

(f) performing nerve conduction studies according to step (c) with said at least one electrode selected in step (e), said nerve conduction studies comprising stimulating said first anatomical site a plurality of times to evoke response signals at said second site, and then processing said evoked response signals to measure one or more of the following parameters of said evoked response signals: distal motor latency,

distal sensory latency, nerve action potential, nerve impulse velocity, amplitude, compound action potential (CMAP) amplitude, F-wave amplitude, F-wave latency, and stimulation threshold.

90. (New) The method of claim 89 wherein time domain features of the response signals are utilized in steps (d) and (e) to determine said at least one electrode.

Remarks

As a result of this amendment, the claims now in the application are claims 24-36, 48-54, 63-74, and 76-90.

In the outstanding Official Action, the Examiner objected to certain language in claims 34, 53, 68 and 74. Those claims have been amended in a manner that is believed to eliminate the language problem noted by the Examiner.

The Examiner also rejected claims 24-36 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This amendment has changed those claims in a manner that Applicants believe eliminate the areas of indefiniteness. Accordingly withdrawal of this ground of rejection is believed to be in order.

Applicants also respectfully request reconsideration of the Examiner's rejections of the claims under 35 U.S.C.103(a) as follows:

(1) claims 24, 26, 31, 35, 36, 48, 54, 63, 69 and 75 as unpatentable over Rosier (4,807,643) in view of Manoli (US 4,583,549) and Battmer et al. (US 6,428,484);

(2) claims 25, 27 and 28 as being unpatentable over Rosier, as modified by Manoli and Battmer et al., further in view of Applicant's submission of prior art;

(3) claims 29, 32, 49, 50, 64, 66, 70 and 71 as unpatentable over Rosier as modified by Manoli and Battmer et al., further in view of Spitz et al. (US 5,215,100); and

(4) claims 30, 33, 34, 51-53, 65, 67, 68 and 72-74 as unpatentable over Rosier as modified by Manoli and Battmer et al., further in view of Drongelen (US 6,224,549).

The foregoing request for reconsideration of the rejections under 35 USC 103(a) is made in view of the changes that have been made to the claims, further in view of the following remarks relative to Applicants invention and the above-identified prior art.

The essence of Applicants' invention is that, by utilization of mechanical and electronic localization, it obviates the need for precise electrode placement and knowledge of neuroanatomy (app. page 14, lines 3-6.). With respect to mechanical

localization, Applicants' sensor is designed to facilitate placement of an evoked response detector in the general vicinity of a muscle or nerve segment to be measured (app. page 13, 18-22). To this end Applicants' sensor is unique in that it combines a stimulator and a detector in one integral unit that is constructed so that when the sensor is located with its stimulator at a first superficial location over a nerve, its detector is oriented relative to the simulator and also automatically positioned in a second superficial location over and in the general vicinity of a second of the muscle or nerve segment that is to be examined (app. page 13, lines 18-21, page 16, lines 21-23, page 17, lines 1-7). In other words, Applicants' sensor is so constructed as to substantially limit the rage of anatomic sites over which the detector can be placed while at the same time automatically placing the detector substantially adjacent to a muscle innervated by a nerve.

With respect to electronic localization, Applicants' invention is adapted to precisely investigate the electro-physiological properties of the region being investigated and to identify the optimal location at which to measure the response evoked by operation of the stimulator, whereby to obtain accurate and reliable measurements (app. page 13, lines 22-23, page 14, lines 1-3). To this end Applicants' invention comprises use of a detector that constitutes a number of electrodes arranged in fixed spatial relationship to one another, and means for sampling the evoked response from all or a section of a muscle and to determine the electrode or combination of electrodes deemed optimal in terms of signal response for performance of nerve conduction studies, all as explained on pages 26-28 of Applicants' specification. In other words, Applicants' invention is configured to evaluate parameters of the signals sensed by the detector and to select those signals which best identify and assess nerve conduction parameters according to the particular neuromuscular pathology that is being evaluated.

The claim changes made by this amendment are intended to better distinguish Applicants' invention from the prior art relied upon by the Examiner. For convenience and in the interest of brevity, the following discussion is concerned primarily with

previously submitted independent claims 24, 48, 63 and 69 (all of which have been amended so as to better define Applicants' invention), but they apply equally well to the claims that depend from those independent claims.

Thus method claim 24 is hereby amended so as to require that the connector be configured to mechanically orient the stimulator and the detector relative to one another and to automatically position the detector substantially adjacent to a second anatomical site when the stimulator is placed substantially adjacent to a first anatomical site on the surface of an individual. Method claim 24 further requires in steps (c) and (d) that the stimulator provide a stimulus to the first anatomical site and the detector detect response signals produced at the second anatomical site, with those signals being processed to evaluate selective parameters of those signals and to compare those response signals according to the evaluated selected parameters. Claim 24 further calls in step (e) for selection of at least one electrode on the basis of the comparison of step (d) which detects a response signal characteristic of the second anatomical site.

Method claim 48 is similar to claim 24 except that it uses different language to characterize the flexile connector. In this case, it calls for a flexible connector that is "constructed and shaped to effect mechanical localization of the detector relative to the stimulator whereby the detector will be automatically positioned substantially adjacent to the second anatomical site where the stimulator is placed substantially adjacent to the first anatomical site". Additionally claim 48 requires evaluating "two or more selected parameters of the response signals" and comparing the response signals according to the evaluated selected parameters for the purpose of selecting at least one electrode detecting a response signal characteristic of the second anatomical site.

Independent apparatus claims 63 and 69 contain language similar to that of claim 24 in defining the connector and its relationship to the stimulator and detector. Claims 63 and 69 also require that the apparatus be configured to effect selection of at least one electrode detecting a response signal characteristic of a second anatomical site. Claim 63 further requires that the selection of the at least one electrode be

accomplished by an algorithm involving evaluation of several parameters of signals detected by the electrodes, while claim 69 calls for the selection of at least one electrode that detects an optimum response signal. In both independent apparatus claims, the connector connects the stimulator to the detector connecter to form an integral structure.

Applicants submit that the several patents relied upon by the Examiner in support of the several Section 103(a) rejections do not render obvious and unpatentable the method and apparatus defined by claims 24, 48, 63 and 69 and also the other previously submitted claims that depend therefrom.

Rosier admittedly discloses apparatus for conducting nerve conduction studies that uses separate stimulus and detector electrodes. However, Rosier does not show or teach the following: (1) a unitary sensor comprising a stimulator, a detector, and a flexible connector physically connecting the stimulator and detector; (2) a plurality of detector electrodes in fixed spatial relation to one another; (3) a connector that orients the detector relative to the stimulator or that automatically positions the detector on a second anatomical site when the stimulator is positioned on a first anatomical site; and (4) means or a method for comparing the responses of several detector electrodes and determining which of the electrodes is positioned to provide an optimum response.

The Manoli patent discloses an electrode pad for passively monitoring a heart's electrical activity. As such the pad comprises several like recording electrodes, but does not teach a stimulator or any relationship with a stimulator. Manoli's apparatus is similar to Applicants' invention in only two respects: (a) it has several electrodes in fixed spatial relationship with one another; and (2) it comprises multiple layers of material including a base layer, and a layer of conductive traces. However, there is no teaching in Manoli relating to nerve conduction studies. Moreover, Manoli does not have multiple electrodes for the same purpose as Applicants, i.e., to determine which of multiple electrodes are positioned to provide an optimum response signal. Therefore, it would

not be obvious to use a flexible multi-electrode pad as taught by Manoli to modify the apparatus or procedures disclosed or rendered obvious by Rosier.

Battmer et al is of interest in that it discloses an implantable device comprising a plurality of electrodes for measuring or picking up auditory evoked potentials, and means including a multiplexer for selecting two of the electrodes that form an optimum couple for picking up evoked potentials. However, Battmer et al. does not teach or suggest construction or use of a sensor that combines a stimulator and a multi-electrode physically connected together in the manner specified by Applicants' claims. Moreover, Battmer et al. do not teach or suggest Applicants' mode of determining the optimum performance electrodes or the use of same to conduct external nerve conductions studies. Therefore, it would not be obvious to combine Battmer et al. with Rosier and Manoli to provide a method or apparatus as taught and claimed by Applicants.

The Examiner's reliance on Applicants' disclosure on pages 13 and 25 relative to relevant nerve conduction parameters is noted, but that disclosure does not suffice to make up for the deficiencies of Rosier, Manoli and Battmer et al.

The patent to Spitz et al. is relevant in that it discloses a device adapted to conduct carpal tunnel nerve conduction studies and teaches peak to peak amplitude measurements of evoked signals. However, Spitz el al. do not teach or suggest Applicants' scheme for (a) determining which of a plurality of electrodes provide optimal responses for particular nerve conduction studies, and (b) then using the electrode(s) found to provide the optimal response to conduct detailed nerve conductions studies. Consequently Spitz el al. does not make up for the deficiencies of Rosier, Manoli and Battmer et al.

Drongelen is relevant because it teaches frequency spectrum comparison. Otherwise, however, the reference does not make up for the deficiencies of the other references discussed hereinabove.

For the foregoing reasons, Applicants submit that their method and apparatus, as defined by claims 24-36, 48-54, and 63-74, are clearly patentable over the prior art.

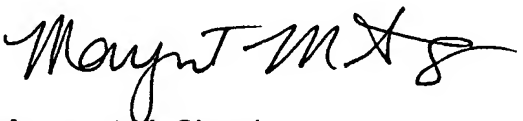
New claims 76-90 are similar to the amended claims and are believed to be patentable for the same reasons. Additionally they add other limitations that distinguish from the prior art relied upon by the Examiner.

This amendment is believed to constitute a full response to the Official Action and to place the application in condition for allowance. Accordingly prompt allowance is respectfully requested.

In the event that any fees may be required in this matter, please charge the same, or credit any overpayment, to Deposit Account No. 16-0221.

Thank you.

Respectfully submitted,



Margaret M. Slezak
Registration No. 55,625
Pandiscio & Pandiscio, P.C.
470 Totten Pond Road
Waltham, MA 02451-1914
Tel. (781) 290-0060

JC2/NEURONRO008.AMD2